2020V_____/RRY/BAW/jw

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Hon.
v.	:	Civil Action. No. 20-
UP TO $3,484,336.98 ON DEPOSIT IN TD BANK ACCOUNT NO. 4340513492 IN THE NAME OF EXPRESS DIAGNOSTICS, AND ALL PROPERTY TRACEABLE TO SUCH PROPERTY,	:	VERIFIED COMPLAINT FOR FORFEITURE IN REM
Defendant in rem.	:	

Plaintiff, the United States of America (the "Government"), by its attorneys, Craig Carpenito, United States Attorney for the District of New Jersey, and Robert Zink, Chief, Department of Justice, Criminal Division, Fraud Section, for its verified complaint (the "Complaint") alleges, upon information and belief, as follows:

I. NATURE OF THE ACTION

1. This action is brought by the Government seeking forfeiture of up to $3,484,336.98 on deposit in TD Bank Account No. 4340513492 in the name of Express Diagnostics, and all property traceable to such property (the "Defendant Property").

II. JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1345 and 1355.

3. Venue is proper pursuant to 28 U.S.C. § 1355(b)(1)(A) because acts and omissions giving rise to the forfeiture took place in the District of New Jersey. Title 28, United States Code, Section 1355(b)(1)(A) provides that a forfeiture action or proceeding may be brought in "the district court for the district in which any of the acts or omissions giving rise to the forfeiture occurred."

4. The Defendant Property is on deposit in an account at TD Bank.

III. BASIS FOR FORFEITURE

5. Express Diagnostics, LLC ("Express Diagnostics") was a New Jersey limited liability company, located in East Brunswick, New Jersey, that purported to serve as a diagnostic testing laboratory. Express Diagnostics was an enrolled Medicare provider and submitted claims to Medicare.

6. Reyad Salahaldeen, a resident of Georgia, Texas, and Washington, obtained control over Express Diagnostics in or around late 2018 and became its Chief Executive Officer. In or around January 2019, Express Diagnostics submitted a Medicare Provider Enrollment Application identifying Reyad Salahaldeen as the Chief Executive Officer and an authorized official.

7. From approximately 2018 to approximately 2020, Express Diagnostics submitted false and fraudulent claims to Medicare for genetic testing that was medically unnecessary, not eligible for Medicare

reimbursement, not provided as represented, and procured through illegal kickbacks and bribes.

8. Reyad Salahaldeen and others, operating through Express Diagnostics, other diagnostic testing laboratories, and a number of shell companies, paid illegal kickbacks and bribes to marketers in exchange for the identification, solicitation, and referral of Medicare beneficiaries for cancer genetic and pharmacogenetic testing that Express Diagnostics billed to Medicare. The marketers used door-to-door solicitation, health fairs, and telephone solicitation to aggressively market testing to Medicare beneficiaries, often paying kickbacks themselves to sub-distributor groups or individual recruiters. DNA swabs were obtained from Medicare beneficiaries without regard to whether beneficiaries had cancer or symptoms of cancer. The genetic testing was ordered without any determination of medical necessity by the beneficiaries' treating physician. The results of the genetic testing frequently were never reported to the beneficiary, rendering them useless for any future course of treatment.

A. The Medicare Program

9. The Medicare Program ("Medicare") is a federally-funded health care program that provides free or below-cost benefits to certain individuals, primarily the elderly, blind, or disabled. The benefits available under Medicare are governed by federal statutes and regulations. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS"), a federal agency within the U.S. Department of Health and Human Services ("HHS").

Individuals who receive Medicare benefits were referred to as Medicare "beneficiaries."

10. Medicare is a "Federal health care program" as defined in Title 42, United States Code, Section 1320a-7b(f), and a "health care benefit program" as defined in Title 18, United States Code, Section 24(b).

11. Medicare is divided into four parts: hospital insurance (Part A), medical insurance (Part B), Medicare Advantage (Part C), and prescription drug benefits (Part D). Part B is a medical insurance program that covers, among other things, medical services provided by physicians, medical clinics, laboratories, and other qualified health care providers, such as office visits, minor surgical procedures, and laboratory testing, that are medically necessary and ordered by licensed medical doctors or other qualified health care providers.

12. Physicians, clinics, laboratories, and other health care providers (collectively, "providers") that provide items and services to Medicare beneficiaries were able to apply for and obtain a "provider number." Providers that receive a Medicare provider number are able to file claims with Medicare to obtain reimbursement for services provided to beneficiaries.

13. When seeking reimbursement from Medicare for provided benefits, services, or items, providers submit the cost of the benefit, service, or item provided together with a description and the appropriate "procedure code," as set forth in the Current Procedural Terminology ("CPT") Manual or the Healthcare Common Procedure Coding System ("HCPCS"). Additionally, claims

submitted to Medicare seeking reimbursement are required to include: (a) the beneficiary's name and Health Insurance Claim Number ("HICN"); (b) the date upon which the benefit, item, or service was provided or supplied to the beneficiary; and (c) the name of the provider, as well as the provider's unique identifying number, known either as the Unique Physician Identification Number ("UPIN") or National Provider Identifier ("NPI"). Claims seeking reimbursement from Medicare are able to be submitted in hard copy or electronically.

14. Medicare, in receiving and adjudicating claims, acted through fiscal intermediaries called Medicare administrative contractors ("MACs"), which were statutory agents of CMS for Medicare Part B. The MACs were private entities that reviewed claims and made payments to providers for services rendered to beneficiaries. The MACs were responsible for processing Medicare claims arising within their assigned geographical area, including determining whether the claim was for a covered service.

15. At all times relevant to this Complaint, Novitas was a MAC that performed administrative services processing and claims payments for Parts A and B of the Medicare program

16. To receive Medicare reimbursement, providers need to have applied to the MAC and executed a written provider agreement. The Medicare provider enrollment application, CMS Form 855B, is required to be signed by an authorized representative of the provider. CMS Form 855B contains a certification that states:

> I agree to abide by the Medicare laws, regulations, and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

17. In executing CMS Form 855B, providers further certify that they "will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

18. Medicare pays for claims only if the items or services are medically reasonable, medically necessary for the treatment or diagnosis of the patient's illness or injury, documented, and actually provided as represented to Medicare. Medicare does not pay for items or services that were procured through kickbacks and bribes.

B. Genetic Testing

19. Cancer genetic tests ("CGx tests") are laboratory tests that use DNA sequencing to detect mutations in genes that could indicate a higher risk of developing certain types of cancers in the future. Pharmacogenetic tests ("PGx tests") are laboratory tests that used DNA sequencing to assess how the body's genetic makeup would affect the response to certain medications, and, together with CGx tests, are referred to as "genetic testing." Neither type of

genetic testing is a method of diagnosing whether an individual has a disease, such as cancer, at the time of the test.

20. To conduct genetic testing, a laboratory must obtain a DNA sample from the patient. Such samples are typically obtained from the patient's saliva by using a cheek (buccal) swab to collect sufficient cells to provide a genetic profile. The genetic sample is then submitted to the laboratory to conduct a CGx or a PGx test.

21. DNA samples are submitted along with requisitions that identify the patient, the patient's insurance, and the specific test to be performed, such as a comprehensive panel of genes to test for risks of multiple cancers. In order for laboratories to submit claims to Medicare, the requisitions have to be signed by doctor or other authorized medical professional who attests to the medical necessity of the test.

22. Medicare does not cover diagnostic testing, including CGx and PGx testing, that is "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Title 42, United States Code, Section 1395y(a)(1)(A). Except for certain statutory exceptions, Medicare does not cover "examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint or injury." Title 42, Code of Federal Regulations, Section 411.15(a)(1). Among the statutory exceptions Medicare covers are cancer screening tests such as "screening mammography, colorectal cancer screening tests, screening pelvic exams, [and] prostate cancer screening tests." Id.

23. If diagnostic testing is necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Medicare imposes additional requirements before covering the testing. Title 42, Code of Federal Regulations, Section 410.32(a) provides, "All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." "Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id.*

C. The Express Diagnostics Account

24. Beginning on or about December 12, 2018, the reimbursements from Medicare that represented payments on the unlawful claims were transferred into TD Bank Account No. 4340513492 in the name of Express Diagnostics ("the Express Diagnostics Account"). According to the account opening materials, this account was opened on or about July 13, 2017. The authorized signers on the account were Reyad Salahaldeen, Mohamad Mustafa, Ayman Mustafa, and a fourth individual. The Government examined records for this account for the period from July 13, 2017, to August 3, 2020.

25. From December 2018 through March 2020, the overwhelming majority of the credits to the Express Diagnostics Account were transfers from Medicare. In the one-year period prior to the filing of this Complaint — i.e., from September 4, 2019 to March 31, 2020, approximately $3,484,336.98 in

reimbursements from Medicare based on fraudulent claims was transferred into the Express Diagnostics Account. A schedule showing these deposits is attached hereto as Exhibit A.

D. The CARES Act

26. The Coronavirus Aid, Relief, and Economic Security ("CARES") Act is a federal law enacted in or around March 2020 and designed to provide emergency financial assistance to the millions of Americans suffering due to the COVID-19 pandemic. Pub. L. 116–136.

27. The CARES Act appropriated $175 billion to the Provider Relief Fund to help health care providers that were financially impacted by COVID-19. The United States Department of Health and Human Services ("HHS"), through its agency, the Health Resources and Services Administration ("HRSA"), oversaw and administered the Provider Relief Fund.

28. The Provider Relief Fund was a "health care benefit program," as defined by Title 18, United States Code, Section 24(b).

29. The Provider Relief Fund was a federally funded program intended to promote financial solvency of health care providers on the front line in the care, treatment, and prevention of COVID-19 by supporting healthcare-related expenses or lost revenue attributable to the novel coronavirus.

30. The Provider Relief Fund issued certain moneys to providers through two phases of General Distributions. In or around April 2020, $30 billion of the Provider Relief Fund was automatically distributed to providers in proportion to the providers' Medicare fee-for-service payments in 2019 through

the first phase. In or around late April 2020, HHS distributed an additional $20 billion to providers based on their share of 2018 net patient revenue through the second phase.

31. Although the deposits occurred automatically, recipients were asked by email or letter to submit an attestation through an online portal confirming receipt of the funds and agreeing to the terms and conditions of the payment ("Terms and Conditions"). Recipients who kept the money for a period that exceeded 90 days from receipt were deemed to have accepted the Terms and Conditions of the fund.

32. Providers who attested to the Terms and Conditions acknowledged that their commitment to full compliance with the terms and conditions was material to the HHS Secretary's decision to disburse Provider Relief Funds to them. Providers further acknowledged that non-compliance with any Term or Condition could cause the HHS Secretary to recoup some or all of the payment.

33. Providers who attested to the Terms and Conditions certified that after January 31, 2020, they provided diagnoses, testing, or care for individuals with possible or actual cases of COVID-19.

34. Providers who attested to the Terms and Conditions also certified that the payment would only be used to prevent, prepare for, and respond to coronavirus, and that the payment would reimburse the recipient only for health care related expenses or lost revenues that are attributable to coronavirus.

35. On April 17, 2020, an electronic funds transfer in the amount of $3,282,305.47 was deposited into the Express Diagnostics Account. The bank statement describes this credit as a "US HHS Stimulus HHS Payment." Express Diagnostics did not submit an attestation agreeing to the Terms and Conditions but, as explained in paragraph 31 above, Express Diagnostics is deemed to have accepted the Terms and Conditions because it has retained the money for a period exceeding 90 days.

36. On or about August 3, 2020, the balance in the Express Diagnostic Account was $3,319,617.97.

IV. CLAIMS FOR FORFEITURE

37. Up to $3,484,336.98 on deposit in the Express Diagnostics Account (*i.e.*, the Defendant Property) is subject to forfeiture to the United States of America pursuant to:

(a) 18 U.S.C. §§ 981(a)(1)(C) and 984, as property, real and personal, that constitutes or is derived from proceeds traceable to a conspiracy to commit health care fraud, contrary to 18 U.S.C. § 1347, in violation of 18 U.S.C. § 1349;

(b) 18 U.S.C. §§ 981(a)(1)(C) and 984, as property, real and personal, that constitutes or is derived from proceeds traceable to a conspiracy to commit wire fraud, contrary to 18 U.S.C. § 1343, in violation of 18 U.S.C. § 1349; and

(c) 18 U.S.C. §§ 981(a)(1)(C) and 984, as property, real and personal, that constitutes or is derived from proceeds traceable to a conspiracy to violate the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(A)-(B), which is a Federal health care offense as defined by 18 U.S.C. § 24(a)(1), by offering and paying kickbacks.

38. Title 18, United States Code, Section 981(a)(2)(A) provides, in pertinent part, that:

> In cases involving . . . unlawful activities . . . the term "proceeds" means property of any kind obtained directly or indirectly, as the result of the commission of the offense giving rise to forfeiture, and any property traceable thereto, and is not limited to the net gain or profit realized from the offense.

39. Title 18, United States Code, Section 984 provides that in any forfeiture action in rem in which the subject property is funds deposited in a financial institution account, it shall not be a defense that the property involved in such offense has been removed and replaced with identical property, so long as the action to forfeit such property is commenced within one year from the date of the offense.

WHEREFORE, plaintiff United States of America prays that process be issued to seize and enforce the forfeiture of the Defendant Property and that all persons having an interest in the Defendant Property be cited to appear and show cause why the forfeiture should not be decreed, and that this Court decree forfeiture of the Defendant Property to the United States of America for

disposition according to law, and that this Court grant plaintiff such further relief as this Court may deem just and proper, together with the costs and disbursements of this action.

Dated: Newark, New Jersey
September 3, 2020

CRAIG CARPENITO
UNITED STATES ATTORNEY
DISTRICT OF NEW JERSEY

By: *s/ Barbara A. Ward*
BARBARA A. WARD
ASSISTANT UNITED STATES ATTORNEY

ROBERT ZINK, CHIEF
U.S. DEPARTMENT OF JUSTICE
CRIMINAL DIVISION, FRAUD SECTION

By: *s/ Rebecca Yuan*
JACOB FOSTER, ASSISTANT CHIEF
REBECCA YUAN, TRIAL ATTORNEY

POST DAT	STATEMENT DESCRIPTION	DEPOSIT AMOU	PAYOR
09/04/19	NOVITAS HCCLAIMPMT 1811484447	$ 725,189.89	CONTRACT (NOVITAS)
09/05/19	NOVITAS HCCLAIMPMT 1811484447	$ 10,402.35	CONTRACT (NOVITAS)
09/12/19	NOVITAS HCCLAIMPMT 1811484447	$ 4,706.64	CONTRACT (NOVITAS)
09/13/19	NOVITAS HCCLAIMPMT 1811484447	$ 4,733.47	CONTRACT (NOVITAS)
09/18/19	NOVITAS HCCLAIMPMT 1811484447	$ 16,451.98	CONTRACT (NOVITAS)
09/19/19	NOVITAS HCCLAIMPMT 1811484447	$ 6,784.25	CONTRACT (NOVITAS)
09/20/19	NOVITAS HCCLAIMPMT 1811484447	$ 16,255.26	CONTRACT (NOVITAS)
09/23/19	NOVITAS HCCLAIMPMT 1811484447	$ 7,098.93	CONTRACT (NOVITAS)
09/24/19	NOVITAS HCCLAIMPMT 1811484447	$ 128,900.07	CONTRACT (NOVITAS)
09/25/19	NOVITAS HCCLAIMPMT 1811484447	$ 305,980.19	CONTRACT (NOVITAS)
09/26/19	NOVITAS HCCLAIMPMT 1811484447	$ 31,732.56	CONTRACT (NOVITAS)
09/27/19	NOVITAS HCCLAIMPMT 1811484447	$ 50,095.04	CONTRACT (NOVITAS)
09/30/19	NOVITAS HCCLAIMPMT 1811484447	$ 78,388.10	CONTRACT (NOVITAS)
10/01/19	NOVITAS	$ 650,197.52	CONTRACT (NOVITAS)
10/02/19	NOVITAS	$ 111,005.22	CONTRACT (NOVITAS)
10/03/19	NOVITAS	$ 164,032.81	CONTRACT (NOVITAS)
10/04/19	NOVITAS	$ 1,297.90	CONTRACT (NOVITAS)
10/09/19	NOVITAS	$ 84,106.55	CONTRACT (NOVITAS)
10/10/19	NOVITAS	$ 5,449.71	CONTRACT (NOVITAS)
10/16/19	NOVITAS	$ 60,423.65	CONTRACT (NOVITAS)
10/18/19	NOVITAS	$ 650,999.42	CONTRACT (NOVITAS)
10/21/19	NOVITAS HCCLAIMPMT 1811484447	$ 11,199.25	NOVITAS SOLUTIONS
10/23/19	NOVITAS HCCLAIMPMT 1811484447	$ 158,841.73	NOVITAS SOLUTIONS
10/24/19	NOVITAS HCCLAIMPMT 1811484447	$ 706.80	NOVITAS SOLUTIONS
10/29/19	NOVITAS HCCLAIMPMT 1811484447	$ 6,090.22	NOVITAS SOLUTIONS
11/05/19	NOVITAS HCCLAIMPMT 1811484447	$ 1,413.85	NOVITAS SOLUTIONS
11/06/19	NOVITAS HCCLAIMPMT 1811484447	$ 1,789.09	NOVITAS SOLUTIONS
11/13/19	NOVITAS HCCLAIMPMT 1811484447	$ 15,783.68	NOVITAS SOLUTIONS
12/02/19	NOVITAS HCCLAIMPMT 1811484447	$ 4,043.21	NOVITAS SOLUTIONS
12/05/19	NOVITAS HCCLAIMPMT 1811484447	$ 22,901.97	NOVITAS SOLUTIONS
12/06/19	NOVITAS HCCLAIMPMT 1811484447	$ 85,634.52	NOVITAS SOLUTIONS
12/10/19	NOVITAS HCCLAIMPMT 1811484447	$ 7,503.82	NOVITAS SOLUTIONS
12/12/19	NOVITAS HCCLAIMPMT 1811484447	$ 36,721.93	NOVITAS SOLUTIONS
12/17/19	NOVITAS HCCLAIMPMT 1811484447	$ 9,420.69	NOVITAS SOLUTIONS
01/27/20	NOVITAS HCCLAIMPMT 1811484447	$ 3,532.47	NOVITAS SOLUTIONS
01/27/20	NOVITAS HCCLAIMPMT 1811484447	$ 29.56	NOVITAS SOLUTIONS
02/05/20	NOVITAS HCCLAIMPMT 1811484447	$ 656.79	NOVITAS SOLUTIONS
02/05/20	NOVITAS HCCLAIMPMT 1811484447	$ 5.50	NOVITAS SOLUTIONS
02/18/20	NOVITAS HCCLAIMPMT 1811484447	$ 472.52	NOVITAS SOLUTIONS
02/20/20	NOVITAS HCCLAIMPMT 1811484447	$ 472.52	NOVITAS SOLUTIONS
03/02/20	NOVITAS HCCLAIMPMT 1811484447	$ 2,885.35	NOVITAS SOLUTIONS
	TOTAL	**$ 3,484,336.98**	

EXHIBIT A

VERIFICATION

I, Isaac M. Bledsoe, hereby verify and declare under penalty of perjury that I am a Special Agent with the United States Department of Health and Human Services, Office of the Inspector General; that I have read the foregoing Verified Complaint for Forfeiture *In Rem* and know the contents thereof; and that the matters contained in the Verified Complaint are true to the best of my own knowledge, information, and belief.

The sources of my knowledge and the grounds of my belief include the official files and records of the United States; information obtained directly by me; and information supplied to me from and by other law enforcement officials, during an investigation of alleged violations of Titles 18 and 42 of the United States Code.

I hereby verify and declare under penalty of perjury that the foregoing is true and correct, pursuant to 28 U.S.C. § 1746.

Dated this 2nd day of September, 2020.

ISAAC M. BLEDSOE, SPECIAL AGENT
U.S. Department of Health and Human Services, Office of the Inspector General